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June 29, 1999

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20857-0003

Re:

Docket No. 98-1265

Dear Sirs

The Food and Drug Administration drafted a memorandum of understanding (MOU) intending to provide legislative guidance to the State Agencies. If the MOU is approved, I, as a consumer, and my doctor, may not have access to compounded drugs which are currently being used by members of my family as effective treatments of serious medical conditions.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of physicians and patients to obtain healthcare products from the provider of their choice, and limits the rights of compounding pharmacists to serve the medical needs of my family and the public's medical needs.

Please note that the MOU must be amended so as to avoid the foregoing limitations.

Very truly yours, Lowin & Zappelle / Dijn

LOUIS S. ZAPPULLA

LSZ/djs

CCI

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